Page 2 of 12

IN THE CLAIMS

The following Listing of Claims should replace all prior versions, and listings, of claims in this Application.

- 1. (Currently amended) A pump device comprising:
- a pump housing,
- a pump cavity formed within the housing, the pump cavity comprising a first wall portion and an opposed second wall portion, the first wall portion having a generally hollow configuration and the second wall portion having a generally raised configuration relative to the pump cavity,
- a pump membrane comprising a first membrane surface and a second membrane surface, the pump membrane being arranged within the pump cavity,
- a pump chamber defined between the first wall portion and the first membrane surface,
- an actuation chamber defined between the second wall portion and the second membrane surface.
- inlet means in fluid communication with the pump chamber,
- outlet means in fluid communication with the pump chamber, wherein
- the pump membrane has a maximum volume position in which the second membrane surface in a stretched state abuts and substantially conforms to the general configuration of the second wall portion, and a drained volume position in which the first membrane surface in a stretched state abuts and substantially conforms to the general configuration of the first wall portion, and
- actuating means for periodically shifting the pump membrane between the maximum volume position and the drained volume position, whereby metering accuracy of the pump device is determined by the first and second wall portions.

Page 3 of 12

- 2. (Previously presented) A pump device as defined in claim 1, wherein the first wall portion has a generally concave configuration and the second wall portion has a generally convex configuration relative to the pump cavity.
- 3. (Previously presented) A pump device as defined in claim 1, wherein the inlet means and the outlet means comprise an inlet valve respectively an outlet valve.
- 4. (Previously presented) A pump device as defined in claim 3, wherein at least one of the valves comprises:
- a valve cavity generally formed from a wall portion and a valve seat portion, the valve seat portion having a generally convex configuration relative to the valve cavity, the valve seat portion comprising a fluid inlet,
- a valve membrane comprising a first valve membrane surface, a second valve membrane surface and a valve opening, the valve membrane being arranged within the valve cavity,
- a valve chamber defined between the first membrane surface and the wall portion, the valve chamber comprising a fluid outlet, wherein
- the valve membrane has a closed position in which the second valve membrane surface in a stretched state abuts and substantially conforms to the general configuration of the valve seat portion thereby closing the fluid inlet, and an open position in which the second valve membrane surface in a further stretched state is at least partially lifted away from the valve seat portion, thereby providing fluid communication between the fluid inlet and the fluid outlet via the valve opening.
- 5. (Previously presented) A pump as defined in claim 3, wherein the pump housing comprises:
- a first housing portion comprising the first wall portion of the pump cavity, and a first portion of at least one of the inlet and outlet valves,
- a second housing portion comprising the second wall portion of the pump cavity, and a

Page 4 of 12

second portion of the at least one of the inlet and outlet valves,

- a membrane member disposed between the first and second housing portions forming the pump membrane and the valve membrane for at least one of the inlet and outlet valves arranged between the first and second portions valve(s).
- 6. (Previously presented) A pump device as defined in claim 1, comprising a fluid conduit in flow communication with the actuation chamber, and actuation means for applying a variable fluid pressure in the actuation chamber for periodically shifting the pump membrane between the maximum volume position and the drained volume position, the actuation means being in flow communication with the actuation chamber through the fluid conduit.
- 7. (Previously presented) A pump device as defined in claim 6, wherein the actuation means comprises means for providing a flow of fluid to the actuation chamber through the fluid conduit to thereby shift the pump membrane from the maximum volume position to the drained volume position, and means for controlling a flow of fluid from the actuation chamber through the fluid conduit to thereby shift the pump membrane from the drained volume position to the maximum volume position.
- 8. (Previously presented) A pump device as defined in claim 6, comprising a fluid chamber in fluid communication with the actuation chamber, and heating means associated with the fluid chamber.
- 9. (Previously presented) A pump as defined in claim 4, wherein a fluid chamber in fluid communication with the actuation chamber is formed between the first and second housing portions, heating means being associated with the fluid chamber.
- 10. (Previously presented) A pump device as defined in claim 6, further comprising:
- a transmission cavity including a moveable transmission member arranged there within,

Page 5 of 12

the transmission cavity comprising an inlet chamber and an outlet chamber sealed from each other by the transmission member, the outlet chamber being in fluid communication with the actuation chamber.

- a fluid chamber in fluid communication with the inlet chamber, and
- heating means associated with the fluid chamber.
- 11. (Previously presented) A pump device as defined in claim 10, wherein the housing comprises:
- a first housing portion comprising the first wall portion of the pump cavity, first portions of the inlet and outlet means, and a first portion of the transmission cavity,
- a second housing portion comprising the second wall portion of the pump cavity, second portions of the inlet and outlet means, and a second portion of the transmission cavity,
- a membrane structure disposed between the first and second housing portions forming the pump membrane, the inlet and outlet valve membranes, and the transmission member.
- 12. (Previously presented) A pump device as defined in claim 7, wherein the means for providing the flow of fluid to the actuation chamber through the fluid conduit is taken from a group consisting of gas expansion means, gas generating means, and gas pumping means.
- 13. (Previously presented) A pump device as defined in claim 12, wherein the means for controlling the flow of fluid from the actuation chamber through the fluid conduit is taken from a group consisting of gas contraction, gas consumption, gas pumping means and gas dumping means.
- 14. (Previously presented) A pump device as defined in claim 6, wherein the actuation means is hydraulic pump means.
- 15. (Currently amended) (Currently amended) A pump device as defined in any of claims 1-4,

Page 6 of 12

comprising actuating means taken from a group comprising a piezoelectric member-(328), and an electrostatic means.

- (Previously presented) A pump device as defined in claim 6, further comprising: 16.
- control means for operating the actuation means at a predetermined priming cycle frequency,
- means for detecting a first membrane movement pattern associated with the pumping of a gas or a mixture of gas and liquid,
- the control means being adapted for continuing operation of the pump in accordance with the priming cycle frequency until a second pre-defined pattern associated with the pumping of a liquid is detected, the control means being adapted to terminate pump actuation in response thereto.
- 17. (Previously presented) A pump device as defined in 6, further comprising:
- control means for operating the actuation means at a predetermined priming cycle frequency.
- means for detecting a membrane movement pattern,
- the control means being adapted for continuing operation of the pump in accordance with the priming cycle frequency until the difference between a series of consecutively detected membrane movement patterns are within a predefined range, the control means being adapted to terminate pump actuation in response thereto.
- (Previously presented) A pump device as defined in claim 16, further comprising 18. detecting means arranged on opposed surfaces of the pump membrane and the housing and providing an electrical impedance which is influenced by movement of the pump membrane relative to the housing, and detection means sensitive to the changes in electrical impedance for providing an output signal representative of movement of the pump membrane.
- 19. (Previously presented) A delivery device comprising:

Page 7 of 12

- pump means comprising a pump device as defined in claim 1,
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the reservoir in a situation of use to be arranged in fluid communication with the inlet means of the pump device, the reservoir preferably being a prefilled, flexible reservoir,
- outlet means being adapted to cooperate with or comprising a transcutaneous access means.
- control means for operating the pump means to expel a drug from the reservoir and out through the outlet means, and
- energizing means for energizing the pump means and the control means.
- 20. (Previously presented) A delivery device as defined in claim 19, further comprising a mounting surface adapted for application to the skin of a subject.
- 21. (Previously presented) A delivery device as defined in claim 20, wherein the mounting surface comprises mounting means having an adhesive surface.
- 22. (Previously presented) A delivery device as defined in claim 20 or 21, wherein the outlet means comprises a hollow infusion needle communicating, in a situation of use, with the interior of the reservoir.
- 23. (Previously presented) A delivery device as defined in claim 22, wherein the infusion needle comprises a distal pointed end adapted to penetrate the skin of the subject, the infusion needle being moveable between a first position in which the pointed end of the needle is arranged in a retracted position relative to the mounting surface, and a second position in which the pointed end of the needle projects from the mounting surface.
- 24. (Previously presented) A delivery device as defined in claim 23, wherein the infusion needle is mounted on a pump assembly comprising the pump device, the pump assembly being

Page 8 of 12

moveable between a first position in which the pointed end of the needle is arranged in a retracted position relative to the mounting surface, and a second position in which the pointed end of the needle projects from the mounting surface.

- 25. (Previously presented) A delivery device as defined in claim 19, wherein the pump means and the reservoir are moveable relative to each other between a first position in which there is no fluid communication between the reservoir and the pump, and a second position in which fluid communication between the reservoir and the pump is established.
- 26. (Previously presented) A drug delivery device as defined in claim 24, wherein movement of the reservoir between a first position and a second position results in movement of the pump assembly between the first position and the second position thereof.
- 27. (Previously presented) A pump device as defined in claim 1, comprising a pump unit and an actuation unit, the pump unit comprising the pump housing, the pump cavity, the pump membrane, the pump chamber, the actuation chamber, the inlet means, and the outlet means, and the actuation unit comprising the actuation means, wherein the units are adapted to be operatively connected to each other.
- 28. (Previously presented) A pump system as defined in claim 27, wherein the pump unit comprises:
- a reservoir for, or containing, a drug to be infused and arranged, in a situation of use, in fluid communication with the inlet means, the reservoir preferably being a prefilled, flexible reservoir, and
- outlet means being adapted to cooperate with or comprising a transcutaneous access means,
- the actuation unit comprising:
- control means for operating the actuation means,

Page 9 of 12

- the pump system comprising energizing means for energizing the actuation means and the control means.
- 29. (Previously presented) A delivery device as defined in claim 19, further comprising:
- indication means,
- detecting means for detecting an occlusion condition associated with a pre-defined elevated pressure condition in the pump chamber during pump actuation, the detecting means being adapted to actuate the indication means when the occlusion condition is detected,
- the outlet means being hydraulically rigid such that a partial or full occlusion of the outlet means will result in a substantially unrestricted pressure rise in the outlet means and thereby the pump chamber.
- 30. (Previously presented) A delivery device as defined in claim 29, wherein the outlet means is in the form of a hollow needle comprising a pointed distal end portion adapted to be inserted though the skin of a subject.
- 31. (Previously presented) A delivery device as defined in claim 29, wherein the occlusion condition associated with a pre-defined elevated pressure condition in the pump chamber is selected from the group comprising the conditions: pressure in the pump chamber, pump membrane position or movement, valve membrane position or movement, pressure in the outlet means, pressure in gas or hydraulic actuation means, position or movement of mechanical actuation means, current flow in electrically driven actuation means.

Page 2 of 12

IN THE CLAIMS

The following Listing of Claims should replace all prior versions, and listings, of claims in this Application.

- 1. (Currently amended) A pump device comprising:
- a pump housing,
- a pump cavity formed within the housing, the pump cavity comprising a first wall portion and an opposed second wall portion, the first wall portion having a generally hollow configuration and the second wall portion having a generally raised configuration relative to the pump cavity,
- a pump membrane comprising a first membrane surface and a second membrane surface, the pump membrane being arranged within the pump cavity,
- a pump chamber defined between the first wall portion and the first membrane surface,
- an actuation chamber defined between the second wall portion and the second membrane surface.
- inlet means in fluid communication with the pump chamber,
- outlet means in fluid communication with the pump chamber, wherein
- the pump membrane has a maximum volume position in which the second membrane surface in a stretched state abuts and substantially conforms to the general configuration of the second wall portion, and a drained volume position in which the first membrane surface in a stretched state abuts and substantially conforms to the general configuration of the first wall portion, and
- actuating means for periodically shifting the pump membrane between the maximum volume position and the drained volume position, whereby metering accuracy of the pump device is determined by the first and second wall portions.

Page 3 of 12

- 2. (Previously presented) A pump device as defined in claim 1, wherein the first wall portion has a generally concave configuration and the second wall portion has a generally convex configuration relative to the pump cavity.
- 3. (Previously presented) A pump device as defined in claim 1, wherein the inlet means and the outlet means comprise an inlet valve respectively an outlet valve.
- 4. (Previously presented) A pump device as defined in claim 3, wherein at least one of the valves comprises:
- a valve cavity generally formed from a wall portion and a valve seat portion, the valve seat portion having a generally convex configuration relative to the valve cavity, the valve seat portion comprising a fluid inlet,
- a valve membrane comprising a first valve membrane surface, a second valve membrane surface and a valve opening, the valve membrane being arranged within the valve cavity,
- a valve chamber defined between the first membrane surface and the wall portion, the valve chamber comprising a fluid outlet, wherein
- the valve membrane has a closed position in which the second valve membrane surface in a stretched state abuts and substantially conforms to the general configuration of the valve seat portion thereby closing the fluid inlet, and an open position in which the second valve membrane surface in a further stretched state is at least partially lifted away from the valve seat portion, thereby providing fluid communication between the fluid inlet and the fluid outlet via the valve opening.
- 5. (Previously presented) A pump as defined in claim 3, wherein the pump housing comprises:
- a first housing portion comprising the first wall portion of the pump cavity, and a first portion of at least one of the inlet and outlet valves,
- a second housing portion comprising the second wall portion of the pump cavity, and a

Page 4 of 12

second portion of the at least one of the inlet and outlet valves.

- a membrane member disposed between the first and second housing portions forming the pump membrane and the valve membrane for at least one of the inlet and outlet valves arranged between the first and second portions valve(s).
- 6. (Previously presented) A pump device as defined in claim 1, comprising a fluid conduit in flow communication with the actuation chamber, and actuation means for applying a variable fluid pressure in the actuation chamber for periodically shifting the pump membrane between the maximum volume position and the drained volume position, the actuation means being in flow communication with the actuation chamber through the fluid conduit.
- 7. (Previously presented) A pump device as defined in claim 6, wherein the actuation means comprises means for providing a flow of fluid to the actuation chamber through the fluid conduit to thereby shift the pump membrane from the maximum volume position to the drained volume position, and means for controlling a flow of fluid from the actuation chamber through the fluid conduit to thereby shift the pump membrane from the drained volume position to the maximum volume position.
- 8. (Previously presented) A pump device as defined in claim 6, comprising a fluid chamber in fluid communication with the actuation chamber, and heating means associated with the fluid chamber.
- 9. (Previously presented) A pump as defined in claim 4, wherein a fluid chamber in fluid communication with the actuation chamber is formed between the first and second housing portions, heating means being associated with the fluid chamber.
- (Previously presented) A pump device as defined in claim 6, further comprising: 10.
- a transmission cavity including a moveable transmission member arranged there within,

Page 5 of 12

the transmission cavity comprising an inlet chamber and an outlet chamber sealed from each other by the transmission member, the outlet chamber being in fluid communication with the actuation chamber,

- a fluid chamber in fluid communication with the inlet chamber, and
- heating means associated with the fluid chamber.
- 11. (Previously presented) A pump device as defined in claim 10, wherein the housing comprises:
- a first housing portion comprising the first wall portion of the pump cavity, first portions of the inlet and outlet means, and a first portion of the transmission cavity.
- a second housing portion comprising the second wall portion of the pump cavity, second portions of the inlet and outlet means, and a second portion of the transmission cavity,
- a membrane structure disposed between the first and second housing portions forming the pump membrane, the inlet and outlet valve membranes, and the transmission member.
- 12. (Previously presented) A pump device as defined in claim 7, wherein the means for providing the flow of fluid to the actuation chamber through the fluid conduit is taken from a group consisting of gas expansion means, gas generating means, and gas pumping means.
- 13. (Previously presented) A pump device as defined in claim 12, wherein the means for controlling the flow of fluid from the actuation chamber through the fluid conduit is taken from a group consisting of gas contraction, gas consumption, gas pumping means and gas dumping means.
- 14. (Previously presented) A pump device as defined in claim 6, wherein the actuation means is hydraulic pump means.
- 15. (Currently amended) (Currently amended) A pump device as defined in any of claims 1-4,

Page 6 of 12

comprising actuating means taken from a group comprising a piezoelectric member-(328), and an electrostatic means.

- 16. (Previously presented) A pump device as defined in claim 6, further comprising:
- control means for operating the actuation means at a predetermined priming cycle frequency,
- means for detecting a first membrane movement pattern associated with the pumping of a gas or a mixture of gas and liquid,
- the control means being adapted for continuing operation of the pump in accordance with the priming cycle frequency until a second pre-defined pattern associated with the pumping of a liquid is detected, the control means being adapted to terminate pump actuation in response thereto.
- 17. (Previously presented) A pump device as defined in 6, further comprising:
- control means for operating the actuation means at a predetermined priming cycle frequency,
- means for detecting a membrane movement pattern,
- the control means being adapted for continuing operation of the pump in accordance with the priming cycle frequency until the difference between a series of consecutively detected membrane movement patterns are within a predefined range, the control means being adapted to terminate pump actuation in response thereto.
- 18. (Previously presented) A pump device as defined in claim 16, further comprising detecting means arranged on opposed surfaces of the pump membrane and the housing and providing an electrical impedance which is influenced by movement of the pump membrane relative to the housing, and detection means sensitive to the changes in electrical impedance for providing an output signal representative of movement of the pump membrane.
- 19. (Previously presented) A delivery device comprising:

Page 7 of 12

- pump means comprising a pump device as defined in claim 1,
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the reservoir in a situation of use to be arranged in fluid communication with the inlet means of the pump device, the reservoir preferably being a prefilled, flexible reservoir,
- outlet means being adapted to cooperate with or comprising a transcutaneous access means.
- control means for operating the pump means to expel a drug from the reservoir and out through the outlet means, and
- energizing means for energizing the pump means and the control means.
- 20. (Previously presented) A delivery device as defined in claim 19, further comprising a mounting surface adapted for application to the skin of a subject.
- 21. (Previously presented) A delivery device as defined in claim 20, wherein the mounting surface comprises mounting means having an adhesive surface.
- 22. (Previously presented) A delivery device as defined in claim 20 or 21, wherein the outlet means comprises a hollow infusion needle communicating, in a situation of use, with the interior of the reservoir.
- 23. (Previously presented) A delivery device as defined in claim 22, wherein the infusion needle comprises a distal pointed end adapted to penetrate the skin of the subject, the infusion needle being moveable between a first position in which the pointed end of the needle is arranged in a retracted position relative to the mounting surface, and a second position in which the pointed end of the needle projects from the mounting surface.
- 24. (Previously presented) A delivery device as defined in claim 23, wherein the infusion needle is mounted on a pump assembly comprising the pump device, the pump assembly being

Page 8 of 12

moveable between a first position in which the pointed end of the needle is arranged in a retracted position relative to the mounting surface, and a second position in which the pointed end of the needle projects from the mounting surface.

- 25. (Previously presented) A delivery device as defined in claim 19, wherein the pump means and the reservoir are moveable relative to each other between a first position in which there is no fluid communication between the reservoir and the pump, and a second position in which fluid communication between the reservoir and the pump is established.
- 26. (Previously presented) A drug delivery device as defined in claim 24, wherein movement of the reservoir between a first position and a second position results in movement of the pump assembly between the first position and the second position thereof.
- 27. (Previously presented) A pump device as defined in claim 1, comprising a pump unit and an actuation unit, the pump unit comprising the pump housing, the pump cavity, the pump membrane, the pump chamber, the actuation chamber, the inlet means, and the outlet means, and the actuation unit comprising the actuation means, wherein the units are adapted to be operatively connected to each other.
- 28. (Previously presented) A pump system as defined in claim 27, wherein the pump unit comprises:
- a reservoir for, or containing, a drug to be infused and arranged, in a situation of use, in fluid communication with the inlet means, the reservoir preferably being a prefilled, flexible reservoir, and
- outlet means being adapted to cooperate with or comprising a transcutaneous access means.
- the actuation unit comprising:
- control means for operating the actuation means,

Page 9 of 12

- the pump system comprising energizing means for energizing the actuation means and the control means.
- 29. (Previously presented) A delivery device as defined in claim 19, further comprising:
- indication means,
- detecting means for detecting an occlusion condition associated with a pre-defined elevated pressure condition in the pump chamber during pump actuation, the detecting means being adapted to actuate the indication means when the occlusion condition is detected,
- the outlet means being hydraulically rigid such that a partial or full occlusion of the outlet means will result in a substantially unrestricted pressure rise in the outlet means and thereby the pump chamber.
- 30. (Previously presented) A delivery device as defined in claim 29, wherein the outlet means is in the form of a hollow needle comprising a pointed distal end portion adapted to be inserted though the skin of a subject.
- 31. (Previously presented) A delivery device as defined in claim 29, wherein the occlusion condition associated with a pre-defined elevated pressure condition in the pump chamber is selected from the group comprising the conditions: pressure in the pump chamber, pump membrane position or movement, valve membrane position or movement, pressure in the outlet means, pressure in gas or hydraulic actuation means, position or movement of mechanical actuation means, current flow in electrically driven actuation means.